Amendments to the Drawings

The attached sheet(s) of drawings includes a replacement drawing sheet of Figure 2 (Sheet 2 of 10 in the pending application) and an annotated drawing sheet showing with changes to correct obvious defects in Figure 2.

Attachment: -Annotated sheets showing changes in Figure 2 pursuant to 37 CFR 1.85 and MPEP 608.02(p).
-Replacement drawing sheets (Sheet 2 of 10)

REMARKS

Applicants wish to thank Examiner Ballard and Supervisory Examiner Andres for the interview of February 16, 2006 in which the outstanding rejections were discussed.

Claims 6-10, 12-41, 62, and 168-206 are pending in the application. Applicants have amended claims 6-7, 13-29 and 32. Support for the amendments can be found throughout the specification and the originally filed claims. In particular, support for amendment to claims 6-7 can be found, for example, at page 33, lines 6-9 and at page 83, lines 22-28. Support for new claim 207 can be found in Example XIII. *No new matter has been added.*

Applicants have amended the figure legends in the specification in order to recite the sequence identifiers of the sequences in the captioned figures. In particular, the figure legends have been amended to include sequence identifiers, preceded by "SEQ ID NO:" as required by 37 C.F.R. 1.821(d). *No new matter has been added.*

Replacement Figure 2 is also submitted with this amendment to correct obvious typographical errors in Original Figure 2. Replacement Figure 2 submitted herewith has been amended to correct the numbering of certain amino acid residues in the sequences listed in original Figure 2 and to remove reference to color as the figure was submitted in black and white. Applicants submit that Replacement Figure 2 submitted herewith *does not constitute new matter.*

Applicants address the remaining objections and rejections as follows:

Applicants thank the Examiners for the thoughtful discussion regarding the outstanding double patenting rejections of record in the instant case. As discussed, cancellation and/or intent to file a terminal disclaimer likely renders moot several of the rejections of record.

i. Statutory Double Patenting

The Examiner maintains the rejection under 35 U.S.C. for provisional statutory double patenting of claims 6-7, 13-31, 33-37 and 39-41 of the instant application over Application No.

10/388,389. Applicants have cancelled claims 1-41 and have amended claim 62 of copending Application No. 10/388,389 such that the provisional statutory double patenting rejection of claims 6-7, 13-31, 33-37 and 39-41 of the instant application is rendered moot. Withdrawal of the rejection claims 6-7, 13-31, 33-37 and 39-41 of the instant application is respectfully requested.

ii. Obvious-type Double Patenting

Claims 32, 38, 62, 169, 171, 173, 175, 177, 179, 181, 183, 185, 187, 189, 191, 193, 195, 197-206 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatenable over claims 32 (including claims 13, 14, 30 and 31) 62, and 15-29 of copending Application No. 10/388,389. Applicants have cancelled claims 32 (including claims 13, 14, 30 and 31) 62, and 15-29 of copending Application No. 10/388,389 such that the provisional obviousness-type double patenting rejection of claims 32, 38, 62, 169, 171, 173, 175, 177, 179, 181, 183, 185, 187, 189, 191, 193, 195, 197-206 of the instant application is rendered moot. Withdrawal of the rejection claims 32, 38, 62, 169, 171, 173, 175, 177, 179, 181, 183, 185, 187, 189, 191, 193, 195, 197-206 of the instant application is respectfully requested.

Claims 6, 7, 13-41, 62, 169, 171, 173, 175, 177, 179, 181, 183, 185, 187, 189, 191, 193, 195, 197-206 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 51, 227-230, 232-248, 251, and 284 of copending Application No. 10/232,030. As indicated in the instant Office Action, a timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Applicants submit that the instant application and copending Application No. 10/232,030 share common ownership. Accordingly, Applicants intend to file an appropriate terminal disclaimer upon an indication of allowable subject matter.

Claims 6, 7, 13, 14, 32-41, 62, 195, and 197-206 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims 1, 2, 5, 9, 23, and 31-40 of co-pending application No. 10/703,713 (herein, "the '713 application").

Applicants respectfully traverse this rejection and request reconsideration and withdrawal on the grounds that claims 6, 7, 13, 14, 32-41, 62, 195, and 197-206 are directed to patentably distinct species of humanized antibodies, antigen binding fragments, or antibody chains, as compared to the antibodies of claims 1, 2, 5, 9, 23, and 31-40 of the '713 application.

As discussed in the interview and reiterated below, it is Applicants position that the claims of the instant case are directed to humanized immunoglobulins having certain structural features that are distinct from the genus of antibodies claimed in the '713 application. In particular, claims 1, 2, 5, 9, 23, and 31-40 of the '713 application are directed to a genus of humanized antibodies (or antigen-binding fragments of said antibodies) having CDRs from the mouse 3D6 antibody and having at least one framework residue in the heavy and/or light chains substituted with the corresponding mouse 3D6 light or heavy chain variable region residue. Substituted framework residues are selected from enumerated categories, namely, residues that non-covalently bind antigen directly, residues adjacent to a CDR, CDR-interacting residues, or residues participating in the VL-VH interface.

In contrast, claims 6, 7, 13, 14, 32-41, 62, 195, and 197-206 of the instant application are directed to patentably distinct species of humanized immunoglobulins, antigen-binding fragments, or antibody chains, wherein at least three framework residues in light and/or heavy chain variable regions are substituted with mouse 3D6 framework residues. Significantly, the claims of the instant application set forth distinct criteria by human framework residues are to be identified for substitution with corresponding mouse framework residues. In particular, claims 6 and 7 of the instant application specify that residues for substitution are those residues capable of affecting the conformation or function of a light or heavy chain as determined by analysis of 3-dimensional model of 3D6 based on particular antibody solved structures (1CR9, 1NLD, 1OPG, and/or 1qkz).

Independent claims 13 and 14 recite that the framework substitution be at at least three sites selected from residue L1, L2, L36, or L46 of the light chain (claim 13) or at least residues H49, H93 or H94 of the heavy chain (Kabat numbering convention) (claim 14). Independent claim 32 recites that the framework substitutions are introduced in both of the light and heavy chains at the aforementioned residues or all residues. Each of dependent claims 33-41, 62, 195, and 197-206 include one or more of these recitations as well as additional differences in subject

matter from claims 1, 2, 5, 9, 23, and 31-40 of the '713 patent which renders the claims patentably distinct. These differences are set forth in each of the dependent claims, the substance of which is reiterated here in support of Applicants' traversal.

Applicants submit that claims 6, 7, 13 14, 32-41, 62, 195, and 197-206 of the instant application are directed to immunoglobulins, immunoglobulin fragments and immunoglobulin chains having structural features that are distinct from those of the antibodies (or antigen-binding fragments) of claims 1, 2, 5, 9, 23, and 31-40 of the '713 application. The Examiner states that the "claims of each application are overlapping in scope; the fragments are merely described differently". That the claims may overlap in scope does not, however, render the claims of the instant application obvious in view of the claims of the '713 application. This is especially true in view of the distinct structural features of the antibodies of the instant claims. The Examiner appears to base this double patenting rejection, in particular, on the overlapping scope of fragments claimed in the '713 claims and the instant claims. Applicants respectfully direct the Examiner's attention to the fact that claims independent claims 6, 7, 13 and 14 do not recite "fragments". Moreover, claim 32 has been amended to indicate that the claimed immunoglobulins and fragments include the recited structural features. Applicants submit that the structural features of claims 6, 7, 13 14, 32-41, 62, 195, and 197-206 of the instant application render the subject matter patentably distinct from that of claims 1, 2, 5, 9, 23, and 31-40 of the '713 application. Accordingly, it is respectfully requested that the obviousness-type double patenting rejection be reconsidered and withdrawn.

iii. Obviousness under 35 USC § 103

Claims 6, 7, 13, 14-41, 62, 169, 171, 173, 175, 177, 179, 181, 183, 185, 187, 189, 191, 193, 195, and 197-206 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Johnson-Wood et al., Proc. Natl. Acad. Sci. USA, February 1997, Vol. 94, pp. 1550-1555 in view of U.S. Patent No. 5,530,101 to Queen et al. and in further view of Frenkel et al., J. Neuroimmunology, July 2000, Vol. 106, pp. 23-31.

The Examiner relies on Johnson-Wood et al. for teaching "a monoclonal antibody 3D6, which is specific for Aβ 1-5 used to determine Aβ and APP immunoreactivities in the PDAPP mouse brain, a transgenic mouse model of Alzheimer's disease." The Examiner recognizes that Johnson-Wood et al. does not teach humanized antibodies but notes that the '101 patent (the Queen patent) discloses "methods for preparing humanized immunoglobulin chains having

generally one or more complementarity determining regions (CDRs) from a donor immunoglobulin and a framework region from a human immunoglobulin." The Examiner states that "[i]t would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the teachings of Johnson-Wood et al. demonstrating the ability of the 3D6 monoclonal antibody to selectively bind to Aβ in the brains of mice to produce humanized antibodies as taught in U.S. Patent 5,530,101 that bind amyloid in humans." The Examiner relies on Frenkel et al. for providing motivation to the person of ordinary skill in the art to produce antibody fragments of light and heavy chain immunoglobulins.

Applicants respectfully traverse this rejection. A proper *prima facie* obviousness rejection requires that the prior art reference (or references when combined) must teach or suggest all the claim limitations. *See* M.P.E.P. § 2143. Even if each and every claim limitation can be found in the prior art reference (or references when combined), there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Additionally, there must be a reasonable expectation of success. *See*, for example, *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1443 (Fed. Cir. 1991) (the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicants' disclosure).

In fact, Applicants note that the Federal Circuit has repeatedly stated that "there is no basis for concluding that an invention would have been obvious solely because it is a combination of elements that were known in the art at the time of the invention." *See*, for example, *Smiths Industries Medical Sys., Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1355, 51 U.S.P.Q.2d 1415, 1423 (Fed. Cir. 1999). The Federal Circuit also recognizes that "virtually all inventions are combinations of old elements . . . . If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue." *See*, for example, *In re Rouffet*, 149 F.3d 1350, 1356, 47 U.S.P.Q.2d 1453, 1459 (Fed. Cir. 1998).

Accordingly, Applicant respectfully submits that it is now well settled law that obviousness cannot be established simply by combining the teachings of the prior art references, absent some teaching or suggestion in the prior art that such a combination can be made. *See* also, for example, *In re Gieger*, 815 F.2d 686, 688, 2 U.S.P.Q.2d 1276, 1278 (Fed. Cir. 1987); *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984).

It is Applicants position that the Examiner has failed to make a proper *prima facie* obviousness rejection. In particular, none of Johnson-Wood et al., the Queen patent, or Frenkel et al., either alone or in combination, teach or suggest the claim limitations of independent claims 6-7 and 13-14 (and remaining claims depending therefrom). Moreover, the prior art references fail to provide the suggestion or motivation, to modify or combine the reference teachings to arrive at the claimed invention or any reasonable expectation of success in arriving at the claimed invention.

The Examiner relies on Johnson-Wood et al. for teaching the mouse monoclonal antibody 3D6, which is used to detect Aβ and APP immunoreactivities in the PDAPP mouse brain. The Examiner relies on Johnson-Wood et al. for teaching various properties of the mouse 3D6 monoclonal antibody. For example, the Examiner states that "the sequences for the CDRs from the 3D6 monoclonal antibody are *intrinsic* properties of the 3D6 antibody". The Examiner further states that "it is an *inherent* property of the 3D6 immunoglobulin light and heavy chains to bind to the same antigen as the original antibody". The Examiner further states that "heavy chain isotype γ1, binding to soluble, aggregated, and disaggregated Aβ, mediating phagocytosis of Aβ, crossing the blood-brain barrier, and reducing both the Aβ burden and neuritic dystrophy in a subject [limitations set forth in Applicants pending claims 36-41] would also all be *intrinsic* properties of immunoglobulin chains derived from the 3D6 antibody".

At pages 9-10 of the Office Action, the Examiner appears to be taking the position that *intrinsic* or *inherent* properties of the mouse 3D6 monoclonal antibody described in Johnson-Wood et al. in some way render the pending humanized antibody claims unpatentable. Such reasoning is not soundly based in any controlling legal principle. While *intrinsic* or *inherent* properties of the mouse 3D6 antibody might be relevant if Applicants were seeking claims directed to the mouse 3D6 immunoglobulins, no such claims are being pursued in the instant case. Rather, humanized 3D6 antibodies are being claimed. The humanized antibodies have CDRs from mouse 3D6 and framework sequences from appropriate human acceptor sequences and selected framework residues substituted from mouse 3D6. As the claimed antibodies by their nature include human acceptor sequences, the structure of the claimed humanized antibodies can not be inherent in the mouse 3D6 antibodies described in Johnson-Wood et al.

As the Examiner is aware, unlike anticipation, obviousness cannot be based on inherency. "That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." *in re Rijkckaert*, 28 U.S.P.Q.2d at 1957 (Fed. Cir 1993). Inherent but

unknown properties of the mouse 3D6 antibody would not have rendered obvious the claimed antibodies.

Furthermore, a *prima facie* case cannot be based merely on alleged functional similarity when the structure of claimed compounds was not suggested by the prior art.

> To be sure, whether a given chemical compound or composition has the same usefulness as closely related materials may be an important consideration in determining obviousness under 35 USC §103. But it is only one consideration. We think the board failed to address itself to other factors which must be given weight in determining whether the subject matter as a whole would have been obvious, namely, whether the prior art suggests the particular structure or form of the compound or composition as well as suitable methods of obtaining that structure or form. The new form of the compound set forth in the claims is as much a part of the "subject matter as a whole" to be compared with the prior art as are other properties of the material which make it useful.
>
> In re Cofer, 148 USPQ 268, 271 (CCPA 1966) (emphasis supplied).

Accordingly, Applicants respectfully submit that Johnson-Wood et al. is quite deficient in teaching or suggesting the claimed antibodies of the instant invention. To cure the deficiencies of Johnson-Wood et al., the Examiner relies on the additional teachings of Queen to arrive at the claimed invention. Applicants submit that contrary to the Examiner's reasoning, Queen fails to cure the deficiencies of Johnson-Wood et al. for at least the following reasons.

The Queen patent is relied on as teaching antibody humanization procedures. Applicants submit, however, that a general teaching of a methodology is insufficient to arrive at the presently claimed humanized antibodies. In particular, the humanized antibodies of claims 6-7 (and claims 15-29 depending therefrom) contain a key structural requirement which is neither taught nor suggested by the Queen patent. Applicants point out that, in addition to requiring CDRs from the 3D6 antibody, independent claims 6-7 require that at least three framework residues within the light or heavy chain be substituted with the corresponding amino acid residues from the mouse 3D6 light or heavy chain, respectively. As recited in the claims, the residues to be substituted are identified by analysis of a three-dimensional model of the mouse 3D6 variable region based on the solved structure of known antibodies, or fragments of known

antibodies. As presently pending, claims 6-7 require that the residues to be substituted are identified by analysis of a three-dimensional model of the mouse 3D6 variable region based on the solved structure of three known antibodies (or antibody fragments). In particular, the model used to identify residues affecting 3D6 light and/or heavy chain conformation or function is based on light chain data (*e.g*, coordinates) from the anti-Gp41 antibody (PDB ID 1NLD), heavy chain data (but for CDR3) from the anti-prion antibody 1F4 (PDB ID 1CR9), and heavy chain CDR3 data from the anti-porin PorA antibody Fab fragment (PDB ID number 1qkz).

The Queen patent makes reference to the modeling of donor antibodies to identify CDR-interacting residues, for example at col. 14, lines 39-44 and at col. 15, lines 43-57. The Examples of the Queen patent state that anti-tac, Fd79, Fd138-80, M195, mik-β1, CMV5 and AF2 antibodies were computer modeled, but does not describe the procedures used to model these antibodies, and in particular, does not teach the selection or source of structural data relied on to model these antibodies.

It is Applicants' position that the Queen patent does not teach or suggest computer modeling of the donor antibody, as described and claimed in the instant application, to select a subset of residues capable of affecting light and/or heavy chain conformation or function as presently claimed. In particular, the Queen patent does not teach or suggest selection of light chain data (*e.g*, coordinates) from the anti-Gp41 antibody (PDB ID 1NLD), heavy chain data (but for CDR3) from the anti-prion antibody 1F4 (PDB ID 1CR9), and heavy chain CDR3 data from the anti-porin PorA antibody Fab fragment (PDB ID number 1qkz), as described and claimed by Applicants. Modeling of the 3D6 antibody based on these particular source data results in a unique 3D6 model from which residues capable of affecting light and/or heavy chain conformation or function are identified.

As discussed in the interview and reiterated herein, identification of residues capable of affecting light and/or heavy chain conformation or function in claims 6-7 depends on a particular modeling of 3D6 variable regions, in particular, based on a combination of solved structure coordinates for the light and heavy chains (with further reliance on yet a different CDR3 solved structure). The selection of solved structure residues for substitution recited in claims 6-7 of the instant application is based on a combination of important criteria designed to identify a subset of residues capable of affecting light and/or heavy chain conformation or function. For example, the structural data (solved structure data) used to generate Applicants' unique 3D6 model were selected based on the source antibody having (1) significant sequence homology to the 3D6 light

or heavy chain amino acid sequences, and (2) the same canonical class as the 3D6 light or heavy chain, with additional solved structure source antibody data chosen for heavy chain CDR3 based on homology to the 3D6 heavy chain CDR3 sequence. Relying on these criteria, light chain data from the anti-Gp41 antibody (PDB ID 1NLD), heavy chain data (but for CDR3) from the anti-prion antibody 1F4 (PDB ID 1CR9), and heavy chain CDR3 data from the anti-porin PorA antibody Fab fragment (PDB ID number 1qkz) were used to model the 3D6 antibody. In failing to teach or exemplify either Applicants' criteria for selecting source antibody data or Applicants' source data relied on, one of ordinary skill could not reasonably expect to arrive at the unique 3D6 model recited in claims 6-7. It follows that one could not reasonably expect to arrive at the claimed antibodies having substitution at the recited subset of residues capable of affecting light and/or heavy chain conformation or function, where identification of such residues is based in the unique 3D6 model. Accordingly, Applicants respectfully submit that the Queen patent fails to teach or suggest the specific humanized 3D6 antibodies recited in claims 6-7 of the instant application.

Moreover, independent claim 13 requires (in addition to CDRs from the 3D6 antibody) that at least three framework residues within the light chain, in particular, at least three of residues L1, L2, L36 or L46 (Kabat numbering convention), be substituted with the corresponding amino acid residues from the mouse 3D6 light chain and independent claim 14 requires that at least three framework residues within the heavy chain, in particular, residues H49, H93 and H94 (Kabat numbering convention), be substituted with the corresponding amino acid residues from the mouse 3D6 heavy chain.

A key structural feature absent from the cited art are the particular variable region framework positions of the 3D6 antibody selected for substitution i.e., at least three positions from the group L1, L2, L36, and L46 (Kabat numbering convention), or positions H49, H93, and H94 (Kabat numbering convention) as recited in pending claims 13 and 14 of the instant application. Applicants submit that although the cited art may disclose general methodologies for identifying potential candidate framework residues for substitution within a human variable region framework, the unique positions of residues identified by Applicants for substitution, which is the subject of the pending claims, is not disclosed or suggested. Moreover, the cited art must provide the suggestion and a reasonable expectation of success to one of ordinary skill in the art to arrive at the claimed humanized antibodies having the particular recited residues for substitution. For the reasons set forth in detail below, the cited art fails to not only provide the

required suggestion, but also the expectation of success to one of ordinary skill in the art to make a humanized antibody having the precise variable region sequences presently claimed.

Queen discusses methods for preparing specific humanized antibodies by substituting acceptor sequences with corresponding sequences from the donor sequence, in one or more of the following categories: (1) they fall within a CDR; (2) they are rare for that position; (3) they are adjacent to one or more CDRs; or (4) they are within about 3°A of the CDR. *See* column 13, line 61 to column 14, line 50. According to Queen, any one of the approximately 80 variable light chain framework residues or approximately 87 variable heavy chain framework residues can be substituted according to those criteria. This disclosure essentially amounts to a genus that encompasses a vast number of species. However, such a disclosure would not provide a specific teaching as to the unique subset of framework residues substituted in the claimed antibodies. Moreover, based on such generalized criteria, one ordinarily skilled in the art would not reasonably expect to succeed at identifying the precise combination of framework amino acid substitutions as presently claimed.

Applicants submit that Queen fails to teach or suggest the claimed subset of variable region framework positions of the 3D6 antibody specified in the claims for substitution. Although Queen does provide general criteria for determining which human variable regions framework residues should be substituted, the actual residues vary for different antibodies, and are determined by molecular modeling of the particular mouse antibody to be humanized. As the Court has made clear, the patentability of a composition claim is determined from the structure of the composition itself and not the existence of a general method for producing such compositions.

> The patentability of a composition claim is determined from the structure of the composition itself and not the existence of a general method for producing such compositions.
> The question becomes whether the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention.
>
> The existence of a general method...is essentially irrelevant to the question whether the specific molecules themselves would have been obvious.
>
> In re Deuel, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995).

Absent teaching of amino acid substitutions at the specific positions recited in the claimed antibodies, the existence of general principles for producing humanized antibodies is thus, "essentially irrelevant," to whether the claimed antibodies themselves would be obvious.

In brief, the cited art would not have allowed contemplation of the acceptor sequences that are incorporated into the claimed humanized antibodies or of the positions recited in the claims for substitution. "What cannot be contemplated or conceived cannot have been obvious" 34 USPQ2d at 1215.

Finally, as discussed in the interview and reiterated herein, Applicants disagree that a skilled person would have been motivated to combine the references. Johnson-Wood et al. describes the characterization of amyloid precursor protein (APP) processing and Aβ deposition in a transgenic model of Alzheimer's disease. The experimentation described in Johnson-Wood et al. involved detection of various APP and Aβ forms using monoclonal or polyclonal antibodies. Brains from *sacrificed* animals were processed for ELISA immunodetection or immunohistochemistry. In Aβ ELISA assays, various antibodies (*e.g.*, 266 and 21F12) were used to specifically detect Aβ forms. Biotinylated 3D6 was used as a reporter agent in certain of these assays. In Aβ immunohistochemistry experiments, biotinylated 3D6 was used detect extent of Aβ deposition in brain sections isolated from various aged mice. Notably, Johnson-Wood uses the 3D6 antibody only for purposes of detection (*i.e., ex vivo* detection) and not for purposes of therapy. Humanization of an antibody as discussed by Queen may be useful for therapy, but no apparent advantage for the detection methods discussed by Johnson-Wood. Because Johnson-Wood discusses 3D6 only for detection and not therapy, the skilled person would not have been motivated to combine its disclosure with that of Queen. Thus, it is respectfully submitted that the rejection should be withdrawn.

In view of the foregoing, Applicants submit that none of the cited references alone or in combination, anticipate or render obvious the claimed invention, and this appears to be the Examiner's own hypothesis. Accordingly, Applicants request that this rejection be reconsidered and withdrawn.

CONCLUSION

If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the examiner is urged to call the undersigned at (617) 227-7400.

Dated: Respectfully submitted,

By _____

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